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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/564,609	01/12/2006	Dmitry Dmitrievich Genkin	06-1663	8872

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EXAMINER	
RAMIREZ, DELIA M	
ART UNIT	PAPER NUMBER
1652	

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01/21/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/564,609	GENKIN ET AL.	
	Examiner	Art Unit	
	DELIA M. RAMIREZ	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 September 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☒ Other: *Wikipidia-antifungal drugs*.

DETAILED ACTION

Status of the Application

Claims 1-4 are pending.

Applicant's amendment of claims 1-4, amendments to the specification, and a new abstract, as submitted in a communication filed on 9/24/2009 are acknowledged.

With regard to the previous election, applicant has indicated that due to a typographical error, the elected subject matter was identified as Group 1 while the intended elected subject matter was that of Group 2. Applicant wishes to clarify the record and has elected Group 2 for further examination on the merits. Applicant also traverses the restriction requirement of 3/19/2009 on the grounds that the Examiner has failed to (1) make a prima facie case requiring such restriction or that the species are unconnected in design, operation or effect, and (2) provide an explanation as to whether the species claimed are in separate classifications, hold separate status in the art or represent a different field of search.

The Examiner acknowledges applicant's clarification. As previously indicated by the Examiner, the election made on 4/17/2009 was construed by the Examiner as being an election of Group 2. As such, the Examiner and applicant are in agreement with the subject matter elected for examination on the merits. With regard to applicant's traverse first presented in the communication filed on 9/24/2009, it is noted that traversal must be presented at the time of election in order to be considered timely. See page 3, item 4 of the Office action mailed on 3/19/2009. In the instant case, applicant's clarification is not considered to be an election but simply reiterating what the Examiner indicated in the Office action mailed on 6/24/2009 with regard to the typographical error made in applicant's communication of 4/17/2009, where an election was already made. See page 2 of the Office action (Status of the application) mailed on 6/24/2009. In addition, even if one were to consider applicant's traverse timely, the instant application is the national stage application of PCT/RU04/00260. As indicated in the restriction

requirement mailed on 3/19/2009, the restriction was required under 35 USC 121 and 372 in accordance with 37 CFR 1.499 and 1.475. The criteria for restriction during the national stage is unity of invention (37 CFR 1.499) and not whether the inventions are patentably independent/distinct as set forth in MPEP 803. The determination of whether unity of invention exists or not does not require an explanation (1) as to whether the species claimed are in separate classifications, hold a separate status in the art, or represent a different field of search, or (2) as to whether the species are unconnected in design, operation or effect. See MPEP 1.475. The Examiner provided a clear explanation in the restriction requirement mailed on 3/19/2009 as to why the claimed invention lacks unity of invention in accordance with MPEP 1.475. It should also be noted that if applicant's position is that the methods to treat the different diseases/conditions recited are not patentably distinct and admits on the record that this is the case, if the Examiner finds one of the species unpatentable over the prior art, that admission may be used in a rejection under 35 U.S.C. 103(a) of the other species. The requirement is deemed proper and therefore is made FINAL.

This application contains subject matter in claims 1-4 (bacterial infections, diseases caused by protozoa, atherosclerosis, diabetes, delated-type hypersensitivity reactions, and diseases caused by mutations in somatic cell's genes) drawn to an invention non-elected with traverse in the communication filed 9/24/2009. A complete reply to the final rejection must include cancellation of the non-elected subject matter or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

Specification

1. The specification remains objected to for the following reasons: (a) the specification at page 10, lines 16-17, as amended on 9/24/2009, recites "Candid albicans and St. Aureus" but it should read "*Candida albicans* and *S. aureus*", and (b) the amendment to the specification filed on 9/24/2009 requires

an amendment to page 10, lines 16-17 (Subgroup 1b (8 mice)....DNA isolation") which should be made instead to page 11, lines 9-13. Appropriate correction is required.

2. The previous objection to the abstract is hereby withdrawn in view of the submission of a new abstract.

Claim Rejections - 35 USC § 112, Second Paragraph

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-4 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. New grounds of rejection is hereby introduced which is necessitated by amendment.

5. Claim 1 (claims 2-4 dependent thereon) is indefinite in the recitation of "the method comprises introduction of blood extracellular DNase enzyme.." because it is unclear as to what the meaning of "blood extracellular DNase enzyme" is. Does applicant mean DNase isolated from broken blood cells? For examination purposes, it will be assumed that the term reads "the method comprises administering a DNase into the systemic blood circulation". Correction is required.

6. Claims 2-4 are indefinite in the recitation of "wherein the blood extracellular DNA destroying agent…" because there is no mention of a blood extracellular DNA destroying agent in claim 1, from which claims 2-4 depend. Correction is required.

7. Claim 2 is indefinite in the recitation of "wherein the blood extracellular DNA destroying agent is a DNase…" because it is unclear as to how it further limits claim 1, from which it depends. Claim 1 already requires a DNase. Does claim 2 further limits claim 1 by requiring an additional DNase which is not the same as that already required in claim 1?. For examination purposes, it will be assumed that claim 2 is a duplicate of claim 1. Correction is required.

Claim Rejections - 35 USC § 112, First Paragraph

8. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

9. Claims 1-4 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

10. Claims 1-4 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for treating *C. albicans* infections wherein said method requires the introduction of DNase in the systemic blood circulation, does not reasonably provide enablement for a method for treating any fungal infection, wherein said method requires the administration of any extracellular DNA destroying agent.

11. These rejections have been discussed at length in the previous Office action. They are maintained for the reasons of record and those set forth below.

12. Applicant argues that if a candidate drug works for candidiasis, it would also work for other minor fungi diseases and cites U.S. Patent No. 5833946 and Katsuhiko et al. as support for this argument. Applicant argues that a particular animal candidiasis model is very highly predictive for efficacy in a variety of human fungi diseases and refers to the patient leaflet of Abelcet in support of the argument that the same compound can be used to treat different infections.

13. Applicant's arguments have been fully considered but are not deemed persuasive to overcome the instant rejection. For the record, while U.S. Patent No. 5833946 has been considered, the reference by Katsuhiko et al. has not been considered since applicant has not provided a copy of such reference. While it may be that some fungicidal compounds are efficient in treating fungal infections from more than one source, one of skill in the art cannot reasonably conclude that any fungicidal compound would work with any type of fungal infection. This is evidenced by the fact that there are many fungicidal compounds in

the market to treat different kinds of fungal infections. See Wikipedia's article on antifungal drugs submitted with this Office action. The instant claims are not limited with regard to the source of fungal infections. Instead, they encompass the treatment of any type of fungal infection in a human being as well as in any organism. The specification provides as the sole working example to support a claim to a method of treatment of fungal infections with DNase, the treatment of mice which have been infected with *C. albicans* (Example 1). There is no teaching or suggestion as to (1) how DNase I acts in an infected animal to clear a fungal infection, or (2) whether the mode of action of DNase I is similar to that of other known fungicidal compounds, such that one of skill in the art could make a determination as to whether the mode of action of DNase I in a *C. albicans* infection would be repeatable with another type of fungal infection or if the same effect could be observed in humans. Even if one assumes that the results obtain with mice with regard to a *C. albicans* infection are repeatable in humans, nothing can be said about which additional fungal infections could be treated as claimed because nothing is known about how DNase I acts in an animal to clear a fungal infection, and neither the specification nor the prior art provides any clue as to which are the fungal infections which are more likely to be treatable with DNase I. Without that knowledge, it is unclear as to how one of skill in the art can determine which fungal infections can and cannot be treated with DNase without testing DNase I for each and every one of possible fungal infections in an animal, including humans. Thus, for the reasons of record and those set forth above, one cannot reasonably conclude that the claimed invention is adequately described or fully enabled.

Claim Rejections - 35 USC § 102

14. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -

> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

15. Claims 1-3 were rejected under 35 U.S.C. 102(b) as being anticipated by Macanovic et al. (Clinical and Experimental Immunology 106:243-252, 1996).

16. This rejection was previously introduced in view of the interpretation of claims 1-3 where the term "in particular…" was not given patentable weight. See the Office action mailed on 6/24/2009 where the interpretation given to these claims was indicated. In view of the fact that claim 1 has been amended to recite specific diseases/conditions and lupus erythematosus is not encompassed by the genus of diseases/conditions recited, this rejection is hereby withdrawn.

17. Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by Sugihara et al. (Br. J. Cancer 67:66-70, 1993). This rejection is necessitated by amendment. Claims 1-2 are directed in part to a method for treating a disease associated with qualitative/quantitative changes in blood extracellular DNA, wherein said disease is a disease caused by mutations in somatic cells' genes, and wherein said method requires the administration of DNase into the systemic blood circulation. Claim 3 is directed to the method of claim 1 wherein the DNase is provided in a dose sufficient to observe a change in extracellular DNA by electrophoresis. Sugihara et al. teach a method for treatment of liver metastasis in mice, which is a disease that results from changes in somatic cells' genes, by administering DNase to mice suffering from liver metastasis (Summary; page 67, left column, Systemic treatment by intravenous enzyme injection). Since Sugihara et al. teach that this treatment resulted in inhibition of liver metastasis (Summary) and that the effect of DNase I on reducing metastasis might relate to disaggregation of tumor cells which adhere to each other by DNA from chromatin of tumor cells that have been destroyed in the circulation (page 69, right column, last three lines-page 70), the method of Sugihara et al. would be expected to reduce the levels of extracellular tumor DNA in blood. In the absence of evidence to the

contrary, one would expect this reduction in extracellular DNA would be detected by electrophoresis. Therefore, the teachings of Sugihara et al. anticipate the instant claims as written.

Conclusion

18. No claim is in condition for allowance.

19. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

20. Certain papers related to this application may be submitted to Art Unit 1652 by facsimile transmission. The FAX number is (571) 273-8300. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If Applicant submits a paper by FAX, the original copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office.

21. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PMR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through

Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

22. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Delia M. Ramirez, Ph.D., whose telephone number is (571) 272-0938. The examiner can normally be reached on Monday-Friday from 9:30 AM to 6:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew J. Wang, can be reached at (571) 272-0811. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

/Delia M. Ramirez/

Primary Patent Examiner
Art Unit 1652

DR
January 21, 2010